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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,207	11/24/2003	Chang Yi Wang	1151-4153US2	8598

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MORGAN & FINNEGAN, L.L.P.
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NEW YORK, NY 10281-2101

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
01/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com
Shopkins@Morganfinnegan.com
jmedina@Morganfinnegan.com

Office Action Summary	Application No.	Applicant(s)	
	10/723,207	WANG ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,7 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 7, and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 10/17/2007 is acknowledged.

2. Claims 3, 7 and 10 are pending.

3. Claims 3, 7 and 10 are currently under examination as they read on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13.

4. The following new grounds of rejection are necessitated by the amendments filed on 09/20/2007 and 10/17/2007.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 3 stands and claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The terms "about 50 to about 90 amino acids", "about 25 to about 29 amino acids" and "about 23 amino acid residues." It is unclear how many amino acids constitute "about". One of skill in the art would not know if applicant meant 4 amino acid, as many as 11 amino acids, or even more.

Applicant's arguments filed on 09/20/2007 have been fully considered, but are not found persuasive.

Applicant argues:

> "Claim 3 was rejected for reciting "about 25 to about 29 amino acids" and "about 23 amino acids". The contention is that the term "about" renders the claim unclear and indefinite in that the term may mean 4, 11 or more amino acids.
>
> Reconsideration is requested for the following reasons.
>
> Firstly, claim 3 adopts language that was used, and discussed with the prior Examiner. The language was regarded as clear and definitely to those of skill in the art.
>
> Secondly, claim 3 recites that SEQ ID NO:5 can vary by up to 4 amino acids. Thus, it is clearr and definite. It is not clear how the Examiner picked the number "11" or more. "

It is the Examiner's position that:

When referring to "about" the Examiner's reference to from 4-11 amino acids is in reference to the variance in the number of amino acids. The term "about" could mean +/-4 amino acids, +/- 11 amino acids or even more. It is completely unclear what the term about means, contrary to Applicant's assertion.

Helper T cell epitopes are typically 12-25 amino acids in length. The recited amino acids sequences for Helper T cell epitopes in claim 10 are 12-39 amino acids in length.

The IgE-CH3 domain peptides of SEQ ID NO:5, 6, 7, 8, and 84 are each 25 amino acids in length. The claim recites that they are 25-29 amino acids in length. However, the claim also recites that one to four of the residues in SEQ ID NO:5 is substitute or deleted, which would make the IgE-CH3 domains 21-25 amino acids in the length, not 25-29 amino acids in length. If the IgE-CH3 domain peptides were 21 amino acids in length, then 2 cysteine residues would not be separated by 23 amino acids. Therefore, the claimed IgE-CH3 domains are indefinite for many reasons.

The immunostimulatory invasin domain, SEQ ID NO:13 is 16 amino acids in length.

Therefore, at a minimum the synthetic peptides of the claimed invention are 33 amino acids in length (12 amino acid helper T cell epitope and a 21 amino acid IgE-CH3 domain having 4 deletions). At a maximum, the synthetic peptides of the claimed invention are 84 amino acids in length (39 amino acid helper T cell epitope (SEQ ID NO:77), a 29 amino acid IgE-CH3 domain (as recited in the claim) and a 16 amino acid immunostimulatory domain). Therefore, what are the 17 and 6 additional amino acids are added, respectively, to the synthetic peptides to make them "about" 50 and "about" 90 amino acids? Does Applicant argue that 33 amino acids is "about" 50 and 84 amino acids is "about" 90?

B. The term "SSAL" in claim 7 is indefinite because it describes the helper T cell epitope as being an arbitrary designation, an 'SSAL.' While SSAL is disclosed in the specification to be a Structured Synthetic Antigen Library, there is no recitation which distinctly claims that limitation. For example, others in the field may isolate a protein and give it the name SSAL, or alternatively 'SSAL' may be read as being a 4 amino acid peptide. Applicants should particularly point out and distinctly claim the 'SSAL' by claiming a sufficient number of identifying characteristics associated. Claiming biochemical molecules by a particular name given to them by various workers in the field fails to distinctly claim them.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 stands and claims 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: the synthetic amino acid peptides of SEQ ID NOS:14-15, 17-23 and 85, which comprise (a) the helper T cell epitope (Th), (b) an IgE-CH3 domain antigen peptide, wherein said IgE -CH3 domain antigen peptide consisting of SEQ ID NO:5; and optionally (c) the immunostimulatory invasin domain consisting of SEQ ID NO:13, does not reasonably provide enablement for a synthetic peptide of **about 50 to about 90 amino acids**, which comprises (a) **a helper T cell epitope** (Th), (b) an IgE-CH3 domain antigen peptide, wherein said IgE -CH3 domain antigen peptide i) is **between about 25 and about 29 amino acids in length** ii) contains two cysteine residues separated by **about 23 amino acid residues**, and iii) is selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:84 and **an immunologically functional analog thereof**, wherein **from one to four of the residues in SEQ ID NO:5 is conservatively substituted or deleted**; and optionally (c) an immunostimulatory invasin domain, SEQ ID NO:13 of claim 3; wherein said Th is an SSAL of claim 7; and wherein said Th has an amino acid sequence selected from the group consisting of SEQ ID NOS: 9-12, SEQ ID NOS: 61-82 and SEQ ID NO:89 of claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons as set forth in the Office Action mailed on 05/21/2007.

Applicant's arguments filed on 09/20/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Claim 3 was rejected for lack of enablement of a synthetic peptide of "about 50 to 90 amino acids". The Examiner picked two of the synthetic peptides presented in the application SEQ ID NO 14 and SEQ ID NO:15, which had 45 or 63 amino acids and contends that there is lack of enablement of about 50 to about 90 amino acids.

Applicant would like to point to Table 4A which presents 18 peptide conjugates as different embodiments of the claimed invention. SEQ ID NO: 20 contains 126 amino acids, SEQ ID NO :27 contains 79 amino acids; SEQ ID NO:87 contains 65 amino acids, SEQ ID NO:88 contains 57 amino acids, SEQ ID NO:19 contains 66 amino acids, SEQ ID NO:90 contains 42 amino acids, and SEQ ID NO:91 contains 61 amino acids. Thus there is ample support for "about 50 to about 90 amino acids."

The Examiner also contends that the specification shows test results for SEQ ID NO:14 and SEQ ID NO:15 and thus does not enable full scope of claim 13. Reconsideration is requested.

It appears that only Table 3 was looked at. Applicant would like to point to Table 2 which provided results of antibodies produced which were cross-reactive with human IgE. There are 15 peptide constructs in accordance with the invention claimed that provided very good cross reactivity. Table 4B also provided results of 6 peptide constructs according to the claimed invention which showed cross reactivity with two of the peptides showing prevention of histamine inhibition. Also Table 7 provided results for inhibition of passive cutaneous anaphylaxis using SEQ ID NO:25.

Thus, it is believed that the claimed invention is enabled. The patent law does not required that each and every embodiment of the invention be tested and the data be presented. Applicant has tested sufficient of the embodiments to show that the invention as claimed is enabled and supported. However, applicant should not be limited by the test results. The test results are illustrative.

Moreover, it is not proper to limit the examination by a restriction requirement, then examine the application for test results limited to the embodiment so restricted. The data in support of the invention as a whole should be considered. Applicant is only required to provide sufficient information and test data to a person of skill in the art to show that the invention as claimed is enabled.

The Examiner points to the unpredictability of protein chemistry. However, the claims are not directed to proteins. The claimed invention is directed to a synthetic peptide comprising of segments with known functions, that of a B-cell epitope and that of a Th epitope. Applicant has developed the B-cell epitope for IgE-CH3. The Th epitopes are well known promiscuous Th-epitopes and those derived therefrom by the

Applicant. Applicants work is based on known principles in immunology and the field of synthetic peptides. See Synhetic Peptides as Antiqens, Ciba Foundations Symposium 119, 1986, pp. 279-291, John Wiley and Sons, a copy of which is enclosed.

Enclosed herewith is copy of Wang et al, Vaccine, 2003, 21:1580-1590. The article shows that the invention claimed has been reviewed by its peers, people of skill in the art, who found the invention to be of merit. In addition, the invention is in the process of being commercialized and is in clinical trials. The publication further shows that to persons of skill in the art the invention as claimed is enabled.

Withdrawal of the rejection on these grounds should be withdrawn."

It is the Examiner's position that at a minimum the synthetic peptides of the claimed invention are 33 amino acids in length (12 amino acid helper T cell epitope and a 21 amino acid IgE-CH3 domain having 4 deletions). At a maximum, the synthetic peptides of the claimed invention are 84 amino acids in length (39 amino acid helper T cell epitope (SEQ ID NO:77), a 29 amino acid IgE-CH3 domain (as recited in the claim) and a 16 amino acid immunostimulatory domain). Applicants do not sufficiently disclose synthetic peptides of "about 50 to about 90 amino acids" as recited in claim 3. The specification does not provide guidance as to which amino acids can be added, substituted or deleted to generate synthtic peptide for use in the claimed invention.

The Examiner appreciates Applicant's pointing to Table 4A and specifically to SEQ ID NO: 20 containing 126 amino acids, SEQ ID NO :27 containing 79 amino acids; SEQ ID NO:87 containing 65 amino acids, SEQ ID NO:88 containing 57 amino acids, SEQ ID NO:19 containing 66 amino acids, SEQ ID NO:90 containing 42 amino acids, and SEQ ID NO:91 containing 61 amino acids for support for "about 50 to about 90 amino acids." However, it is

the Examiner's position that Applicant's argument actually supports the Examiner's position and not Applicant's position. SEQ ID NO:20 having 126 amino acids and SEQ ID NO:90 with 42 amino acids do not provide support for "about 50 to about 90 amino acids." SEQ ID NO:20 and SEQ ID NO:90 exemplify the problem that the Examiner has with the phrase. There is not adequate guidance in the specification as to what "about" means and further there is not adequate guidance as to what amino acids may be added or deleted in the peptide conjugates that are encompassed in the instant invention.

It is further the Examiner's position that the claims read on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13. Contrary to Applicant's assertion that "it is not proper to limit the examination by a restriction requirement, then examine the application for test results limited to the embodiment so restricted.", the Examiner is not obligated to extend the search and examination within a Markush claim when the elected or subsequent species is rejected under any of 35 USC 101, 102, 103 or 112 1st. Therefore, the Examiner is only considering the enablement of the claims as they read on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13 at this time.

The Examiner has evaluated Tables 2, 4B and 7, as suggested by Applicant. However, there are no peptides in Tables 2 and 7 which are encompassed by the invention that is currently being examined as it reads on a synthetic peptide immunogen of about 50 to about 90 amino

acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13. Table 4B provided results of 2 peptide constructs according to the claimed invention which showed cross reactivity with two of the peptides showing prevention of histamine inhibition and they have been added to what is enabled by the specification's disclosure.

It remains the Examiner's position that the specification does not disclose support for the recited "helper T cell epitope (Th)." This recitation includes all helper T cell epitopes, including undiscovered T cell epitopes from undiscovered antigens. The specification's disclosure does not provide enablement for the use of any helper T cell epitope in the instant invention.

Further, the specification does not disclose support for the 'an immunologically functional analog' of SEQ ID NO:5, 'wherein from one to four of the residues in SEQ ID NO:5 is conservatively substituted or deleted.' The specification's disclosure does not provide enablement for the use of any analog or mutant of SEQ ID NO:5 in the instant invention. The specification fails to provide sufficient guidance as to which core structure of SEQ ID NO: 5 is essential for maintain its use in the claimed immunogen for inhibiting histamine release and which changes can be made in the structure of SEQ ID NO: 5 and still maintained the same function. Mutations in the conserved patterns without much change in the overall sequence would lead to a change in the essential structure and therefore to a change in function. Therefore, absent the ability to predict which of these polypeptides would function as claimed, and given the lack of data on regions critical for activity, for one of skill in the art to practice the invention as claimed would require a level of experimentation that is excessive and undue.

Applicant's assertion that the claimed invention is directed to a synthetic peptides comprising of segments with known functions, that of a B-cell epitope and that of a Th epitope, that Applicant has developed the B-cell epitope for IgE-CH3, and that the Th epitopes are well known promiscuous Th-epitopes makes the claimed invention not unpredictable. In response, the Examiner would like to call Applicant's attention to page 38, line 21 to page 39, line 35 of the specification. Applicant's own disclosure states that the art of IgE cross-reactivity is unpredictable. Therefore, Applicant's current argument that it is not is unpersuasive.

The postdated article by Wang et al, Vaccine, may show that the invention has been reviewed by people of skill in the art who found the invention to be of merit and that it is in the process of being commercialized and in clinical trials. However, Wang et al. does not show that the invention is enabled by the specification as filed. That is the standard upon which the Examiner relies in making the instant rejection.

8. Claim 3 stands and claims 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: the synthetic amino acid peptides of SEQ ID NOS:14-15, 17-23 and 85, which comprise (a) the helper T cell epitope (Th), (b) an IgE-CH3 domain antigen peptide, wherein said IgE -CH3 domain antigen peptide consisting of SEQ ID NO:5; and optionally (c) the immunostimulatory invasin domain consisting of SEQ ID NO:13.

Applicant is not in possession of: a synthetic peptide of **about 50 to about 90 amino acids**, which comprises (a) **a helper T cell epitope** (Th), (b) an IgE-CH3 domain antigen peptide, wherein said IgE -CH3 domain antigen peptide i) is **between about 25 and about 29 amino acids in length** ii) contains two cysteine residues separated by **about 23 amino acid residues**, and iii) is selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:84 and **an immunologically functional analog thereof**, wherein **from one to four of the residues in SEQ ID NO:5 is conservatively substituted or deleted**; and optionally (c) an immunostimulatory invasin domain, SEQ ID NO:13 of claim 3; wherein said Th is an SSAL of claim 7; and wherein said Th has an amino acid sequence selected from the group consisting of SEQ ID NOS: 9-12, SEQ ID NOS: 61-82 and SEQ ID NO:89 of claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons as set forth in the Office Action mailed on 05/21/2007.

Applicant's arguments filed on 09/20/2007 have been fully considered, but are not found persuasive.

Applicant argues:

"Claim 3 was rejected for lack of enablement of a synthetic peptide of "about 50 to 90 amino acids". The Examiner picked two of the synthetic peptides presented in the application SEQ ID NO 14 and SEQ ID NO:15, which had 45 or 63 amino acids and contends that there is lack of enablement of about 50 to about 90 amino acids.

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Thus, it is believed that the claimed invention is enabled. The patent law does not required that each and every embodiment of the invention be tested and the data be presented. Applicant has tested sufficient of the embodiments to show that the invention as claimed is enabled and supported. However, applicant should not be limited by the test results. The test results are illustrative.

Moreover, it is not proper to limit the examination by a restriction requirement, then examine the application for test results limited to the embodiment so restricted. The data in support of the invention as a whole should be considered. Applicant is only required to provide sufficient information and test data to a person of skill in the art to show that the invention as claimed is enabled.

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Enclosed herewith is copy of Wang et al, Vaccine, 2003, 21:1580-1590. The article shows that the invention claimed has been reviewed by its peers, people of skill in the art, who found the invention to be of merit. In addition, the invention is in the process of being commercialized and is in clinical trials. The publication further shows that to persons of skill in the art the invention as claimed is enabled.

Withdrawal of the rejection on these grounds should be withdrawn."

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It is further the Examiner's position that the claims as they read on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13. Contrary to Applicant's assertion that "it is not proper to limit the examination by a restriction requirement, then examine the application for test results limited to the embodiment so restricted.", the Examiner is not obligated to extend the search and examination within a Markush claim when the elected or subsequent species is rejected under any of 35 USC 101, 102, 103 or 112 1st. Therefore, the Examiner is only considering the written description of the claims as they read on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13 at this time.

The Examiner has evaluated Tables 2, 4B and 7, as suggested by Applicant. However, there are no peptides in Tables 2 and 7 which are encompassed by the invention that is currently being examined as it reads on a synthetic peptide immunogen of about 50 to about 90 amino acids comprising a helper T cell epitope, SEQ ID NO:5 and optionally SEQ ID NO:13. Table 4B provided results of 2 peptide constructs according to the claimed invention which showed

cross reactivity with two of the peptides showing prevention of histamine inhibition and they have been added to what Applicant possesses in the specification's disclosure.

It remains the Examiner's position that the specification does not describe the recited "helper T cell epitope (Th)." This recitation includes all helper T cell epitopes, including undiscovered T cell epitopes from undiscovered antigens. The specification's disclosure does not describe the use of any helper T cell epitope in the instant invention.

Further, the specification does not describe 'an immunologically functional analog' of SEQ ID NO:5, 'wherein from one to four of the residues in SEQ ID NO:5 is conservatively substituted or deleted.' The specification's disclosure does not describe any analog or mutant of SEQ ID NO:5 in the instant invention. The specification fails to provide sufficient guidance as to which core structure of SEQ ID NO: 5 is essential for maintain its use in the claimed immunogen for inhibiting histamine release and which changes can be made in the structure of SEQ ID NO: 5 that still maintain the same function. Mutations in the conserved patterns without much change in the overall sequence would lead to a change in the essential structure and therefore to a change in function.

Applicant's assertion that the claimed invention is directed to a synthetic peptides comprising of segments with known functions, that of a B-cell epitope and that of a Th epitope, and that Applicant has developed the B-cell epitope for IgE-CH3, and that the Th epitopes are well known promiscuous Th-epitopes makes the claimed invention not

unpredictable. In response, the Examiner would like to call Applicant's attention to page 38, line 21 to page 39, line 35 of the specification. Applicant's own disclosure states that the art of IgE cross-reactivity is unpredictable. Therefore, Applicant's current argument that it is not is unpersuasive.

The postdated article by Wang et al, Vaccine, may show that the invention has been reviewed by people of skill in the art who found the invention to be of merit and that it is in the process of being commercialized and in clinical trials. However, Wang et al. does not show that the invention is adequately described by the specification as filed. That is the standard upon which the Examiner relies in making the instant rejection.

Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See University of Rochester, 358 F.3d at 927, 69 USPQ2d at 1895. "Without a correlation between structure and function, the claims do little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement." Ex parte Kubin, 83 U.S.P.Q.2d 1410 (BPAI 2007). The specification does not adequately describe the genus of all synthetic pepetides of about 50 to about 90 amino acids, which comprise (a) a helper T cell epitope (Th), (b) an IgE-CH3 domain antigen peptide, wherein said IgE -CH3 domain antigen peptide i) is between about 25 and about 29 amino acids in length ii) contains two cysteine residues separated by about 23 amino acid residues, and iii) is selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:84 and an immunologically functional analog

thereof, wherein from one to four of the residues in SEQ ID NO:5 is conservatively substituted or deleted; and optionally (c) an immunostimulatory invasin domain, SEQ ID NO:13 for use in the claimed invention.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher M. Haddad

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